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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,649	09/21/1999	ANDREW J. SZABO	SZABO-201.1	3645

7590 01/07/2004

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EXAMINER	
RIMELL, SAMUEL G	

ART UNIT	PAPER NUMBER
2175	36

DATE MAILED: 01/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/400,649	SZABO, ANDREW J.	
	Examiner	Art Unit	
	Sam Rimell	2175	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-33 and 35-74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-33, 35-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

SAM RIMELL
PRIMARY EXAMINER

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 51: In line 3, the phrase "the determined risk model" lacks antecedent basis.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 51, 60 and 67-73 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 51: The original disclosure contains no mention of a "risk model", as described in the third line of the claim. Although the disclosure does discuss the element of risk, there is no mention of a "risk model".

Claim 60: The original disclosure does not state that the "likelihood of adoption" is part of the optimization process, or is a variable in the optimization process.

Claim 67: The original disclosure does not state that the "likelihood of adoption" is a variable in a joint analysis.

Claims 68-73: Claims 68-73 depend from claim 67.

Claims 51, 60 and 67-73 are considered to contain new matter and will not be further examined on the merits.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-33, 35-50, 52-59, 61-66 and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Mayaud (U.S. Patent 5,845,255).

Claim 29: FIG. 7 of Mayaud discloses a user interface which receives input from a user in the form of a medical condition to evaluate records (medications) for prescription to a patient. In the case of FIG. 7, the user input is the condition "PUD/Gastritis". A subset of records (suggested medications) are then automatically created based upon the classification of information (formulary/non-formulary drugs) and the user input ("PUD/Gastritis").

As described at col. 39, lines 43-54, the system allows determination of economic parameters (cost of a drug) and allows physician to select a drug or block of drugs based on cost.

As described at col. 39, lines 55-67, the initially selected drug can be evaluated in accordance with the patient's history record. That record includes a listing of drug allergies (col. 19, lines 28-30). Drug allergies are a statistical risk associate with a record of a drug in a database.

The resulting output is shown in FIG. 11, and will include a drug or drug that has been automatically (by computer) optimized for both the risk to the patient and the economic cost.

This is considered to be an automatic optimization since it is performed by the assistance of a computer program, and a joint optimization since it considers two separate variables.

Claim 30: The user input ("PUD/Gastritis") is health information.

Claim 31: Col. 19, lines 28-30 call for the input of patient allergies, which reads as an input of data pertaining to risk tolerance.

Claim 32: FIG. 7 is a user interface.

Claim 33: The economic parameters which are considered (col. 39, lines 44-54) pertain to cost.

Claim 35: The user input ("PUD/Gastritis") is a semantic expression.

Claim 36: In FIG. 7, the user can input a preference, such as a preference for formulary or non-formulary medications.

Claim 37: The user feedback is a selection of a drug for a patient. If the user receives warnings about that drug (col. 40, lines 1-19), the drug selection can be cancelled and another drug selection made.

Claim 38: Col. 39, lines 44-54 outline a plurality of different optimization procedures which can be followed.

Claim 39: Col. 9, lines 44-45 call for the creation of an electronic prescription which is transmitted electronically to a pharmacy. This inherently leads to the transaction of a sale of a medication at a pharmacy.

Claim 40: The transmission of the electronic prescription is a transmission between a server (206) and a client computer at a pharmacy.

Claim 41: The system of Mayaud utilizes the Internet (col. 48, line 2).

Claim 42: The system of Mayaud is implemented by a network of a computer systems each containing programmed instructions for controlling the respective computers.

Claim 43: FIG. 7 is a graphic user interface.

Claim 44: See claim 29. The user relevance parameter is the input of ("PUD/Gastritis") by the user in FIG. 7.

Claim 45: See remarks for claim 30.

Claim 46: The facility (206) functions as a search engine for searching databases (210, 212).

Claim 47: See remarks for claim 41.

Claim 48: See remarks for claim 33.

Claim 49: Col. 40, lines 1-10 discuss the presentation of drugs, as well as choices of alternative drugs that can be presented to the user. These choices are presented based upon the user input of risks (allergies/interactions) and economic parameters (cost).

Claim 50: The input of a disease by a user, such as "PUD/Gastritis" pertains a population grouping, since a population of patients can have this disease.

Claim 52: See remarks for claim 37.

Claim 53: See remarks for claim 38.

Claim 54: See remarks for claim 39.

Claim 55: See remarks for claim 40.

Claim 56: See remarks for claim 41.

Claim 57: See remarks for claim 42.

Claim 58: See remarks for claim 43.

Claim 59: See remarks for claim 29. The "specification" is the indication of disease "PUD/Gastritis" by the user in FIG. 7.

Claim 61: See remarks for claim 38.

Claim 62: Col. 19, line 30 calls for the input of a relevance profile (allergic reaction information).

Claim 63: See remarks for claim 39.

Claim 64: See remarks for claim 41.

Claim 65: See remarks for claim 42.

Claim 66: See remarks for claim 43.

Claim 74: Col. 39, line 50 illustrates that the economic parameters are dictated by an external third party (benefit management company).

Remarks

Applicant's arguments have been considered.

Applicant's amendments have overcome the previous grounds of rejection under 35 USC 112, second paragraph, although a new grounds of rejection under 35 USC 112, second paragraph is necessitated by the amendment to claim 51.

Examiner has considered applicant's arguments and amendments with respect to the rejection of claim 51 under 35 USC 112, first paragraph. While Examiner agrees that the term "risk tolerance" as amended is within the disclosure, the term "risk model" still remains in the last portion of the claim. Thu, the rejection of this claim under 35 USC 112, first paragraph is maintained.

Examiner has considered applicant's arguments and amendments with respect to the rejection of claims 60 and 67-73 under 35 USC 112, first paragraph. In this issue, examiner does not entirely agree with the arguments presented. While Examiner does agree that the word "likely" and the phrase "likely to be adopted" appears in the disclosure at page 19, lines 13-19, they are not described as being one of the variables in the optimization process itself. In particular, page 19, line 14 simply states that a certain type of final proposal is likely to be rejected. This does not state that the likelihood is part of the optimization process itself, or a variable in a joint analysis. Similarly, page 19, line 7 merely states that simple changes in diet are likely to be adopted. This does not state the adoption likelihood is made part of the optimization process itself or is a variable in a joint analysis. Accordingly, the rejection of claims 60 and 67-73 under 35 USC 112, first paragraph are sustained.

Examiner has considered applicant's arguments and amendments with respect to the rejection of claims 29-33, 35-50, 52-59, 61-66 and 74 as being anticipated under 35 USC 102(e) by Mayaud. Applicant argues that Mayud does not disclose an automatic joint optimization of variables. Examiner maintains that Mayaud does have this feature. In particular, col. 39, lines 43-54 describe drug cost as an economic parameter that is first considered. Then, in col. 39, lines 55-67, the patient's history is considered. Since the patient's history includes a statistical risk (risk of allergy), this becomes the statistical risk parameter in the optimization process. The system then makes a drug selection upon consideration of all the input parameters, not just one parameter. Thus the optimization is jointly based upon all of the input parameters, not just one single parameter. The optimization is automatic by reason that it is performed with the assistance of a computer program.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to Sam Rimell at telephone number (703) 306-5626.

Sam Rimell
Primary Examiner
Art Unit 2175